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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,941	02/21/2006	Michael Horstmann	RO4150US (#90568)	7611

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,941	HORSTMANN ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-28* is/are pending in the application.

4a) Of the above claim(s) *2-10 and 14-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1, 12-13, 24, 26-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants' Remarks and Amended Claims filed on June 14, 2010 is acknowledged. Claims 1-10, 12-28 are pending in this application. Claims 2-10, 14-23, and 25 are withdrawn from consideration as reading on non elected subject matter. Therefor, claims 1, 12-13, 24, and 26-27 are under prosecution in this application.

Newly submitted claims 19 and 25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons they contain additional components which are not required in the originally represented claims and are drawn to a kit type system comprising more than one of the devices originally claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19, 25, and 28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has inquired as to the status of claim 3, Claim 3 remains withdrawn are being drawn to non-elected species. Applicant has elected the combination of L-dopa and an anticholinergically active substance. L-dopa is Levodopa, which is a dopamine antagonist; therefore the additional election of a dopamine agonist is not necessary.

Applicant has amended claim 5 to depend from a non elected group, a dopamine agonist and an anticholinergically active. However, it is noted that L-dopa is a dopamine

agonist, and therefore, claim 5 will be considered to the extent that it reads on L-dopa and an anticholinergically active agent.

Priority Documents

A certified copy of the foreign priority documents has been filed in the instant application on February 21, 2006. However, a certified English translation has not been received. It appears Applicant has submitted a new copy of the specification on June 14, 2010, in English. However, it does not appear to be a received English translation. Applicant's attention is directed to the requirements for submission of a certified English translation in MPEP 201.15 which requires a statement that the translation of the certified copy is accurate. The Examiner notes however, that at the present time, a certified English translation is not required to overcome any rejection of record and therefore an English translation is not required at this time.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicants amendment to the claim to recite the combination of the active substances are contained together in the layer or compartment.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 5, and 12 under 35 U.S.C. 102(b) as being anticipated by El-Rashidy et al. (US Patent 6,193,992) has been withdrawn in view of Applicants arguments. It is also noted that the rejection did not recite Applicants elected combination of L-dopa and an anticholinergically active substance.

The rejection of claims 1, 5, and 12 under 35 U.S.C. 102(b) as being anticipated by Schoenleber et al. (US Patent 4,963,568) has been withdrawn in view of Applicants amendment to claim 1 to recite specific anticholinergically active substances.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 5, and12 under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US Patent 5,614,178) has been withdrawn in view of Applicants amendment to claim 1 to recite specific anticholinergically active agents which are not explicitly disclosed in Bloom.

The rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over El-Rashidy et al. (US Patent 6,193,992) in view of Reed Jr. (US Patent 4,877,618), or in the alternative, Schoenleber et al. (US patent 4,963,568) in view of Reed Jr. (US Patent 4,877,618) has been withdrawn for the same reasons as outlined above for El-Rashidy and Schoenleber, respectively.

Newly Applied Rejections/Objections

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant has amended claim 5 to recite specific anticholinergically active agents. However, as discussed above, Applicant has elected to prosecute the combination of l-dopa and an anticholinergically active agent. It is noted that L-dopa is a dopamine agonist and therefore, claim 5 does not further limit the scope of claim 1 as it relates to the elected specie.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 12, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US Patent 5,614,178).

Bloom et al. disclose transdermal devices comprising an active agent (abstract). The agent can be selected from numerous classes of drugs, including anti-cholinergic drugs such as scopolamine, atropine, and levodopa (L-Dopa) (column 5, lines 50-55). Bloom et al. additionally disclose the use of muscle relaxants, including orphenadrine (column 8, lines 10-16).

Bloom et al. additionally disclose that combinations of active agents can be employed to provide more than one benefit (column 4, lines 52-55).

Bloom et al. further disclose that the active agents are contained in an effective amount depending on the drug, the ability of the drug to permeate the skin, the particular condition being treated, and the age and physical condition of the patient. Therefore, it is the position of the examiner that based on this teaching; the skilled artisan would be able to determine the effective dosage amount/range through routine experimentation.

Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See In re Russell, 439 F.2d 1228 169 USPQ 426(CCPA 1971).

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined an anti-cholinergical drug and a muscle relaxant since they both reduce spasms of muscles.

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining

them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of anti-cholinergic drugs. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). It would have been obvious to the skilled artisan at the time the invention was made to have combined two known agents which are used for the same purpose into a transdermal device.

Claims 13, 24, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US Patent 5,614,178) in view of Andriola et al. (US Patent 4,666,441).

The teachings of Bloom et al. are discussed above and applied in the same manner.

Bloom et al. do not disclose the orientation of the transdermal device.

Andriola et al. disclose a multi-compartmentalized transdermal patch.

It would have been obvious to one of ordinary skill in the art at the invention was made to have utilized the patch of Andriola et al. because they disclose the advantages of the patch allows one to flexibly utilize drug formulations giving greater range of release rates and more precisely control drug delivery to the skin by utilizing different drug concentrations, different vehicles, different additives such as flux enhancers, and different materials having different drug transference rates (column 3, lines 57-68).

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615